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Basics of FDA Regulation of Medical Devices

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Presentation Outline

- Statutory Authority
- Definition of “Device”
- Device Classification
- Major Regulatory Pathways
- *In Vitro* Diagnostic Devices
- Combination Products
- Registration and Listing/ US Agent
- Device Master File (DMF)
- Component Supplier
- Quality System Regulation (QSR)
- Postmarket Studies/MDR Reporting
- User Fees

What is a "Device"?

- An instrument, apparatus, implement, machine, contrivance, implant, *in-vitro* reagent
- Intended to:
  - Diagnose disease/conditions;
  - Aid in the cure, mitigation, treatment, or prevention of disease;
  - Affect the structure/function of the human body; and
- Does not achieve primary purpose through chemical action;
- Is not dependent upon being metabolized

Classification of Devices

- Risk-based and knowledge-based scheme that provides reasonable assurance of safety and effectiveness
- Determines the extent of regulatory control applied to the device
- Classified within 16 medical specialties in accordance with 1976 medical device law; largely based upon preamendment devices
  - FDA has classified and described over 1,700 generic types of devices
- Reclassification: statute permits any interested party to petition to reclassify a device
- *De novo* classification process may be available

Regulatory Pathways

- Most widely utilized
  - Premarket Notification (510(k)) for Class I/II
  - Premarket Approval (PMA) for Class III
- Less commonly utilized
  - Product Development Protocol (PDP) for Class III (an alternative to PMA)
  - Humanitarian Device Exemption (HDE) for Class II/III
  - *De novo* for Class II


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